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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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JAMES C. LYDON				
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SUITE 100				
ALEXANDRIA, VA 22314				
EXAMINER				
SIMMONS, CHRIS E				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/534,988

Applicant(s)

LEINO ET AL.

Examiner

CHRIS E. SIMMONS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16, 19-22 and 28-30 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 16, 19-22 and 28-30 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Unless maintained infra, all previous rejections are withdrawn.

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Applicant's submission of the 1.132 declaration was sufficient to overcome the anticipation by USP 5,494,676, necessitating this obviousness rejection over same. The declaration illustrated that compositions of USP 5,494,676 are not necessarily of a pH between 6.1 and 7.0.

Claims 16, 19-22, and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over USP 5,494,676 in view of WO 02/07520.

The term "non-dissociated" is being interpreted by the Examiner to mean some non-dissociated form of the compound is present and "complete" dissociation is not required. Furthermore, some non-dissociated form of cis-urocanic acid would be present since there is an equilibrium between dissociated and non-dissociated forms, especially at neutral pH (7.0).

The primary reference teaches the method of treating inflammatory diseases, including psoriasis, comprising administering a topical composition (column 1, line 15) comprising cis-urocanic acid (col. 1, line 50-end). As for the limitation, "capable of acidifying cell cytoplasm", any agent is "**capable** of acidifying cell cytoplasm", especially a diprotic acid such as cis-urocanic acid - having pKa values of 3.9 and 7.03 - which is non-dissociated and dissociated in a composition at a pH between 6.1 to 7.0. Therefore, there are molecules of the acid form that are available to donate protons to the cytoplasm thereby acidifying its environment. This reference differs from the claim insofar as being silent about the final pH of the composition.

The secondary reference discloses advantages of using topical compositions at a relatively neutral, which are fewer problems with irritation to the skin (WO 02/07520, page 4, lines 15-18.

The skilled artisan would have found it obvious to use the composition of the primary reference at a pH that is near or at neutral because the composition would be beneficial at such pH as to minimize irritation to the skin when –especially when treating already irritated psoriatic keratinocytes as disclosed in the reference.

Claims 16, 19-22, and 28-30 are rejected under 35 USC 103(a) as being unpatentable over Ben-Basset et al. ("*Inhibitors of Tyrosine Kinases in the Treatment of Psoriasis*"; Current Pharmaceutical Design, 2000, Vol. 6 No. 9: 933-942) in view of WO 02/07520.

Ben-Basset et al. discloses the treatment of psoriasis by administering tyrosine kinase inhibitors such as, AG 18 (p. 938 under Group II; page 939 column 2, second paragraph). Ben-Basset et al. does not disclose expressly the pH range from 6.1-7.0.

As for the limitation, "capable of acidifying cell cytoplasm", any agent is "**capable** of acidifying cell cytoplasm", especially a diol with acidic properties such as AG 18 - having a pKa value of 7.24 - which is non-dissociated and dissociated in a composition at a pH between 6.1 to 7.0. Therefore, there are molecules of the diol that are available to acidify the cytoplasm.

At the time of the invention it would have been obvious to a person of ordinary skill in the art to treat a disease characterized by local inflammatory reaction such as

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psoriasis by administering a near neutral composition comprising AG 18. The suggestion/motivation for doing so would have been to provide such a composition at an optimal pH at which the agent would have the desired effect and outcome. Additionally, a pH near neutral would cause minimal irritation to the skin.

Applicant's arguments have been fully considered but are not deemed to be found persuasive for reasons set forth in the prior office action and for reasons herein. Applicant is arguing against teachings of a reference (i.e., Dvir et al.) that is not part of the prior rejection. It appears Applicant has chosen to argue this reference to show the mechanism of the anti-psoriatic effects caused by AG 18. However, such limitation is not required by the claims, rendering the arguments incommensurate in scope with the claims.

Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16, 19-22, and 28-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-18 and 20-23 of copending Application No. 11/408,056 in view Granstein Psoriasis (Further Evidence of a Key Role for Leukocytes. J. Clin. Invest. Volume 98, Number 8, October 1996, 1695-1696).

Applicant argues that the application is in condition for allowance and, therefore, the rejection should be withdrawn. After fully considering the arguments, the Examiner does not find them to be persuasive.

Claims 16, 19-22, and 28-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-21 and 23-26 of copending Application No. 10/565,202 in view Granstein Psoriasis (Further Evidence of a Key Role for Leukocytes. J. Clin. Invest. Volume 98, Number 8, October 1996, 1695-1696).

Applicant argues that the application is in condition for allowance and, therefore, the rejection should be withdrawn. After fully considering the arguments, the Examiner does not find them to be persuasive.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **CHRIS E. SIMMONS** whose telephone number is

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(571)272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Chris E Simmons/
Examiner, Art Unit 1612

**/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612**